

## REMARKS

### CLAIMS

#### 35 U.S.C. § 112 ¶ 2 Rejection of Claims 1 - 4, 16 - 30, and 37 - 41

The Office Action rejected Claims 1 - 4, 16 - 30, and 37 - 41 under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to delete “/or”. New Claim 42 was added to claim the alternative situation.

Claims 1 and 37 have been amended to delete the word “optionally”. New Claims 43 - 45 were added to claim this feature.

Claim 3 was amended to delete the repeated phrase.

Claims 2 - 4, 16 - 30, and 38 - 41 are dependent from the amended claims.

The Examiner is requested to withdraw the 35 U.S.C. § 112 ¶ 2 Rejection of Claims 1 - 4, 16 - 30, and 37 - 41. In light of the foregoing amendments, the Examiner is respectfully requested to allow Claims 1 - 4, 16 - 30, and 37 - 41.

#### 35 U.S.C. § 102(b) Rejection of Claims 1 - 4, 16, 17, 31, 32 - 34, 37 - 39, and 41

The Office Action rejected Claims 1 - 4, 16, 17, 31, 32 - 34, 37 - 39 and 41 under 35 U.S.C. 102(b) as being anticipated by Phan *et al.* (U.S. Patent No. 5,603,722) [Phan ‘722].

Independent Claims 1 and 37 have been amended to more clearly claim the disclosed stent. The disclosed stent has a SMP with “two stimulus-triggered shapes in memory”. The stent disclosed in Phan ‘722 has only one stimulus-triggered shape in memory and this is not really a “memory shape” but actually a shape upon relaxing when soft. The “high curvature” shape present during insertion is only possible by mechanical force upon the heated flat “memory shape”. Once cooled, the “high curvature” shape remains until the stent is heated after insertion. The “high curvature” shape expands to assume a “low-curvature” shape once the stent meets resistance from the blood vessel. The stent in Phan ‘722 is unable to return to the “high curvature” shape or any other secondary shape.

The Examiner is requested to withdraw Phan '722 as a 102(b) Prior Art reference. In light of the foregoing arguments, the Examiner is respectfully requested to allow Claims 1 - 4, 16, 17, 31, 32 - 34, 37 - 39, and 41.

35 U.S.C. § 103(a) Rejections of Claims 18 – 27, 30, 35, 36 and 40

Claims 18 – 27

The Office Action rejected Claims 18 – 27 under 35 U.S.C. 103(a) as being unpatentable over Phan *et al.* (U.S. Patent No. 5,603,722). The Office Action states “Phan *et al.* discloses the invention substantially as claimed except for the e-module of the SMP material, the reset fixation value of the SMP material, or the reset ratio of the SMP material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an SMP material with the above limitations and the ranges as recited in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In *re* Aller, 105 USPQ 233.” Applicants disagree with the conclusion of the Office Action and Traverse.

The Office appears to have either misunderstood or misapplied “*in re* Aller”. *In re* Aller pertains to a situation where a range for a particular parameter (e.g., temperature of conducting a method) has been disclosed in a reference and the applicant has claimed a specific temperature or range within the previously disclosed range in the reference.

This is very different from the features in Claims 18 – 27 which are qualities to be achieved in the disclosed stent. These features are improvements to the quality and performance of the stent, not “discovering the optimum or workable ranges involv[ing] only routine skill in the art”. For example, it is not “routine skill in the art” to make a “SMP with a reset fixation value of more than approximately 90%” as in Claim 24 or as in any of the other features in Claim 18 - 27.

Under the stated reasoning in the Office Action, every invention would be blocked by *in re* Aller as they all represent “discovering the optimum or workable ranges” for that discovery.

Claims 28, 30, and 40

The Office Action rejected Claims 28, 30, and 40 under 35 U.S.C. 103(a) as being unpatentable over Phan *et al.* (U.S. Patent No. 5,603,722). The Office Action states the same reasons as above for the other 35 U.S.C. § 103(a) rejections.

Applicants disagree with the conclusion of the Office Action for the same reasons as stated above and Traverse.

The discovery of the particular compounds and materials that enable the achievement of the desired results in a composition is not “routine skill in the art” but requires the investigation of the specific reactions with an assortment of compounds and materials to achieve the desired qualities in the composition.

Additionally, Claim 30 has been amended to claim the features as “qualities” rather than as “processes”.

#### Claims 35 and 36

The Office Action rejected Claims 35 and 36 under 35 U.S.C. 103(a) as being unpatentable over Phan *et al.* (U.S. Patent No. 5,603,722). The Office Action states “it would have been obvious to have used the same methods in forming the stent to reduce the size of the stent in the vessel in order for it to be removed. Since the stent can be delivered by using one of the recited stimuli, it would be obvious to use the same stimuli, but in reverse, to remove the stent”.

Applicants disagree with the conclusion of the Office Action for the same reasons as stated above and Traverse.

The Office Action misstates the facts in Phan ‘722 and makes a conclusion not supported by the disclosure. The statement “the stent can be delivered by using one of the recited stimuli, it would be obvious to use the same stimuli, but in reverse, to remove the stent” is not true. First, it is unknown what is meant by “same stimuli, but in reverse”. Phan ‘722 discloses a stent that becomes soft when warmed so that it expands. Is the reverse of this stimulus “cold” and if so, have does the stent getting hard from being cold make it return to a “high curvature” shape, when the “high curvature” shape is not a memory shape. The Office Action has confused what is “wished for” with what is possible. It is impossible to remove the stent disclosed in Phan ‘722 by using the “same stimuli, but in reverse”.

#### Claims 18 – 27, 30, 35, 36 and 40

Applicants note the Office has made an apparent attempt to officially notice facts to support the rejections of Claims 18 – 27, 30, 35, 36 and 40. If the Office has intended to take Official

Notice, such an attempt is traversed, at least because it is not in compliance with the Office's own procedures.

Proper use of Official Notice requires compliance with several obligations expressly set forth in the "Manual of Patent Examining Procedure". The Office has failed to meet these obligations. Specifically, the Office has failed to satisfy its obligations under MPEP § 2144.03. MPEP § 2144.03 (B), for example, expressly requires the Office to provide specific factual findings predicated on sound technical and scientific reasoning to support taking Official Notice. Naked assertions about what is allegedly known in the art, like those made at pages 3 - 5 of the Office Action, cannot satisfy these requirements.

Applicant respectfully traverses the rejections of Claims 18 - 27, 30, 35, 36 and 40, at least because the Office has failed to establish a *prima facie* case of obviousness.

Official Notice is only proper for facts. (MPEP § 2144.03). Specifically, Official Notice is only permissible for those few facts that are of a "notorious character" and that are "capable of instant and unquestionable demonstration". (MPEP § 2144.03(A)). It is improper to use Official Notice for conclusions of law.

Additionally, the Office Action relies on Official Notice as the "principal evidence" upon which the rejections are based. Official Notice cannot be used in this manner. As Section 2144.03(A) of the MPEP expressly warns, it is never appropriate to rely solely on Official Notice as the principal evidence upon which a rejection was based. Instead, Official Notice is only appropriate for facts and that serve to "fill in the gaps" in a rejection. (MPEP § 2144.03(A)). Therefore, official notice is to be judicially applied. (MPEP § 2144.03).

Finally, the Office attempts to take Official Notice of matter that is not "capable of instant and unquestionable demonstration", as expressly required by section 2144.03(A) of the MPEP. The courts have long rejected the notion that official notice can be taken on the state of the art. (See "Memorandum to Patent Examining Corps from the Deputy Commissioner for Patent Examining Policy regarding Procedures for Relying on Facts Which are Not of Record as Common Sense or for Taking Official Notice", n.6, citing *In re Eynde*, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973)). Thus, the Office's attempt to officially notice the level of ordinary skill in the art is improper as a matter of law.

Applicants respectfully traverse this attempted use of Official Notice as improper and traversed. Consequently, there are evidentiary gaps in the rejections of the claims that are fatal to a *prima facie* case of obviousness.

The Examiner is requested to withdraw Phan '722 as a 103(a) Prior Art reference. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 18 – 27, 30, 35, 36 and 40.

## Conclusion

Claims 1 – 4 and 16 – 45 are pending. Claims 1, 3, 4 and 16 - 41 are Currently amended. Claims 42 – 35 are New. Claims 2 and 5 – 15 are Canceled.

In view of the foregoing, Applicants respectfully request reconsideration and timely allowance of the pending claims. Additionally should the Examiner feel that there are any issues outstanding after consideration of this response; the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 that is not accounted for in the enclosed transmittal, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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